Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 5/17/2019 9:30:08 PM
To: Dunn, Alexandra [dunn.alexandra@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]
CC: Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Tyler, Tom [Tyler.Tom@epa.gov]
Subject: FW: LINDA: Questions on chemicals, deadline of Monday

Reporter would like as much as we have on Monday – w/any remaining Tues am. My counterpart is sharing with ORD management now.

Black type is from OPPT
Red type is from ORD

GENERAL QUESTIONS

1. 1. While the EU bans or restricts more than a thousand chemicals, the US bans 11. What is EPA's comment on the discrepancy?

   The EU and US have different chemical management laws and regulations. Under amended TSCA, EPA must now conduct risk evaluations on existing chemicals to determine if the chemical presents an unreasonable risk. If unreasonable risk is found then the Agency can impose restrictions that could include banning or restricting a chemical's distribution. Prior to amended TSCA EPA was not required to evaluate the risks or impose any restrictions on existing chemicals. Under section 5 of TSCA , EPA conducts reviews of new chemicals, i.e., those not currently in commerce. When risks are identified as part of this review, EPA may restrict, limit particular uses or even ban commercialization until further information is developed. These restrictions are reflected in Consent Orders and Significant New Use Rules (SNURs) Statistics regarding EPA's regulation of new chemicals can be found here: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review and here: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review

2. 2. Can EPA comment on assertions that former industry officials now making decisions on chemical regulations at EPA have a conflict of interest? Nancy Beck worked for ACC, Erik Baptist worked for API, Peter Wright for Dow Chemical, David Dunlap for Koch Industries and Steven Cook for LyondellBasell Industries. They each work on chemicals at EPA. How do they avoid a conflict of interest?

   Political – OPS will answer.

3. 3. Separately, one expert argues EPA is relying more on cellular-level studies (conducted in petri dishes) often developed in partnership with industry. She says EPA is doing this rather than using rodent studies. She calls it a "complete disaster." Can EPA comment?

   For those chemicals being evaluated for risk under TSCA, the Agency is required to look at the weight of scientific evidence and is utilizing a systematic review approach to evaluate all reasonably available information. This approach does not skew towards one type of study over another.

EPA's research laboratories use multiple approaches to assess risks from chemical exposure. These include computational approaches, biochemical- and cellular-based studies, organotypic culture systems ("organ on a chip), and animal studies. The biochemical- and cellular-based studies are largely being used to screen and prioritize chemicals for further testing using more complex systems, including animal studies. Thus, EPA is using a much more integrated, tiered approach wherein initial screens allow us to design more targeted animal studies, thus reducing and refining our use of animals in research. In addition, we still rely on animal studies when we suspect the risk involves adverse effects on complex systems such as reproduction and development for which we have few if any reliable biochemical- and cellular-based assays. The driver for implementing this type of approach is the simple fact that given the number of chemicals in commerce that require risk evaluation and the time required for a complete animal study, hundreds of years and millions of animals would be needed to complete such studies and obtain answers regarding chemical safety.

TCE

4. 4. Does EPA maintain TCE is carcinogenic to humans by all routes of exposure?

In 2011, EPA's Integrated Risk Information System (IRIS) Program concluded that TCE is carcinogenic to humans by all routes of exposure. At present, the EPA is conducting a current risk evaluation for TCE under amended TSCA to determine risks to humans: (https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten).

5. 5. My reporting and research indicate the American Chemistry Council repeatedly requested EPA suspend 2014 guidelines for accelerated cleanup at TCE sites. EPA's Patrick Davis said no but that the agency might reconsider that decision as part of a different process. ACC later met with Kell Kelly. Does EPA have plans to relax this guidance?
OLEM will answer

6. 6. ACC and the Halogenated Solvents Industry have argued the studies EPA relies on for TCE guidelines are not sound, including one linking heart malformations in utero to the chemical. Does EPA currently rely on that study? Is EPA reconsidering relying on that study?

OPPT is currently conducting a risk evaluation on TCE to determine the risks to humans. The draft risk evaluation will be released this summer. The Agency is required to look at the weight of scientific evidence and is utilizing a systematic review approach to evaluate all reasonably available information. We will base the use of a specific study on the results of the systematic review process.

7. 7. Will EPA make any further decisions about whether to move forward with the Obama administration's proposed restrictions for certain uses of TCE?

OPPT is currently conducting a risk evaluation on TCE to determine the risks to humans. If unreasonable risks are found then the Agency will move to limit the risks, including determining if the proposed rules are appropriate.

8. 8. What is EPA doing to help states address TCE plumes around the country?
OLEM will answer

9. 9. Outside experts argue that EPA is using the updates to TSCA to undermine ongoing reviews. Can you comment?

When a risk evaluation is conducted under TSCA, EPA evaluates not only the hazard of the chemical, but the hazard in the context of known and reasonably foreseen exposures. Upon completion of this statutorily mandated 3 year process, a risk evaluation will tell the public whether or not specific uses of the chemical present an unreasonable risk.

Completed IRIS assessments are used as a tool that can inform regulation by various stakeholder groups, including EPA but do not force any risk management action. TSCA both ensures robust scientific assessments and also requires that the Agency expeditiously mitigate risks through regulatory action. An IRIS assessment does not have similar authority, nor does it have any timelines for completion of the scientific evaluation itself.

FORMALDEHYDE

10. 10. In a January 2018 letter, ACC criticized the agency's handling of formaldehyde rules. That summer, news broke that the government had been stalling the release of a report that most Americans inhale enough of the chemical to be at risk for leukemia. Did EPA advise withholding the study? Has ACC's criticism informed EPA's decisions around formaldehyde?
Political – OPS will answer.

11. 11. The letter was signed by ACC's Kimberly Wise White, who is now on EPA's science advisory board. Does Ms. White have to recuse herself from any activities she has previously lobbied the agency on?

From Tom Brennan/SAB: Before the Science Advisory Board (SAB) takes on any peer review or consultation activity, all the Board members are evaluated for potential conflicts of interest. It is not uncommon that Board members recuse themselves from certain portions of the SAB's work portfolio. These decisions are made on a project-specific, case-by-case basis based on the work before the Board.

12. 12. Will the formaldehyde review be overseen by former ACC executive Nancy Beck? How will she avoid a conflict of interest?
Political – OPS will answer.

HEXAVALENT CHROMIUM

13. 13. In a recent science scoping meeting, ToxStrategies on behalf of ACC questioned a foundational study of cement workers that EPA relies on that connected the chemical to cancer. Will EPA continue to rely on this study?

The studies referenced by ToxStrategies (Suh et al., 2019 and Deng et al., 2019) are both meta-analyses. Per earlier NAS recommendations (NRC, 2011), rather than relying upon existing external meta-analyses, IRIS conducts its own meta-analyses in instances where they may be useful in assessing causation. We routinely evaluate references in existing meta-analyses to ensure that no appropriate literature is missed in our analyses. In the case of hexavalent chromium, we will consider the references in the meta-analyses ToxStrategies highlighted in their presentation (Suh et al., 2019 and Deng et al., 2019), but we will not be relying on the results of their analyses. In addition, we will conduct an updated literature search as we proceed with assessment development.

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From: Strauss, Linda
Sent: Thursday, May 16, 2019 4:09 PM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Cc: Dunton, Cheryl <Dunton.Cheryl@epa.gov>
Subject: for awareness - doozy press Q's FW: LINDA: Questions on chemicals, deadline of noon Monday

See below questions 1- 13. OPA already has answers to some of these questions (conflicts of interest); some are OLEM/ORD/. I'm figuring out who has lead on which ones now. I've told OPA to please press hard to get an extension. Linda 240-461-8231

From: Emily Holden <emily.holden@theguardian.com>
Sent: Thursday, May 16, 2019 3:35 PM
To: Press <Press@epa.gov>
Cc: Konkus, John <konkus.john@epa.gov>
Subject: Questions on chemicals, deadline of noon Monday

Hello,

I plan to write and publish a piece about industry lobbying against regulations on chemicals, including: trichloroethylene, formaldehyde and hexavalent chromium.

I would like to pose the following questions to EPA and make you aware of assertions made about the lobbying process by: outside experts, Americans impacted by chemical exposure, and campaigners who argue for increased regulations.

The deadline for me to include your response is **Noon ET on Monday, May 20**.
If you have any questions, please call me at 225-284-8303.

As well, I ask that you **please confirm receipt** of this message, or I will note that you declined to comment.

Please see below.

Thank you,
Emily

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